Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC., Plaintiff, v. NATERA, INC., Defendant.	)	C.A. No. 19-662 (CFC)

NATERA'S SURREPLY BRIEF IN OPPOSITION TO CAREDX'S MOTION FOR A PERMANENT INJUNCTION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Rules

INTRODUCTION

CareDx's revised proposed injunction does not cure the fatal deficiencies of its original proposal—one that indisputably did not comply with Federal Rule of Civil Procedure 65.[1] CareDx's attempted do-over, presented for the first time with its Reply Brief, proposes a completely different—but still noncompliant—injunction. Its proposal should be rejected in the first instance because it is untimely under D. Del. LR 7.1.3(c)(2). More fundamentally, it remains overbroad, and lacks the specificity required by the Federal Rules. CareDx's revised proposed injunction would restrain or chill lawful speech, and threatens to transform this Court into a permanent arbiter of scientific reliability for as long as these products remain in competition, obliging the Court to weigh in each time new research is released.

Even if the Court does not grant Natera's Motion for JMOL, a narrower injunction would adequately protect CareDx's interests. CareDx contended that two kinds of statements were "literally false": (1) certain "unreliable" comparisons between results reported in the Sigdel paper ("Sigdel") and the Bloom paper ("Bloom"); and (2) an implicit "claim" that Prospera had high sensitivity in patients 18 years old and under, based on data in Sigdel. An order limited to those "claims," as outlined in Section I, *infra*, would prohibit Natera from repeating the claims found

[1] CareDx asserts that it "is not conceding that its initial Proposed Order was overbroad" (D.I. 363 at 2 n.1) but does not explain how that Proposed Order was compliant with Rule 65 or cite any authority permitting a plaintiff to ignore it.

by the jury to be false. CareDx's unacceptable revised injunction, by contrast, would restrain lawful speech and impose burdensome, unreasonable obligations on Natera and the Court.

ARGUMENT

Contrary to CareDx's assertion, Natera fundamentally disputes CareDx's entitlement to an injunction for the reasons set forth in its JMOL motion. (D.I. 340, 348.) Pending resolution of the parties' post-trial motions, however, Natera has removed the claims at issue from its website and marketing materials. Should the Court agree that CareDx failed to adduce sufficient evidence of falsity or any other element of its claims, no injunction is warranted.

Even if this Court excuses CareDx's failure to submit an appropriate injunction with its opening brief, *but see, e.g.*, *Align Tech., Inc v. 3Shape A/S*, No. 17-cv-1647-LPS, 2020 WL 5979353, at *3 (D. Del. Oct. 8, 2020) ("The Court will not evaluate the merits of this contention because it is untimely and waived." (citing LR 7.1.3)), CareDx's second try at a Proposed Order remains impermissibly overbroad. Among other things, CareDx continues to seek an injunction that would enjoin advertising claims that were never addressed at trial, and are neither false nor misleading.

In contrast, the Court would adequately address the claims found to be false by entering an injunction limited to (i) the statements at issue (ii) insofar as they

relied upon the Sigdel paper. Such an injunction would supply "the narrowest remedy possible" to avoid stifling lawful speech and fair competition or enlisting the Court as a roving board of scientific review. *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 599 (3d Cir. 2002).

I. CAREDX'S REQUESTED INJUNCTION REMAINS IMPERMISSIBLY OVERBROAD.

CareDx's revised proposed order corrects only its most glaring violation of Federal Rule of Civil Procedure 65(d): it no longer incorporates the Jury Verdict Form by reference. (D.I. 363-1.) But the revised injunction still runs afoul of Rule 65's requirements that it "state its terms specifically" and "describe in reasonable detail . . . the act or acts restrained." Fed. R. Civ. P. 65(d).[2]

CareDx's arguments fail for three main reasons:

[2] Although CareDx's revised proposed order does not seek an injunction for "claims that are not colorably different from the False Advertising Claims," CareDx continues to defend such a request. *Compare* D.I. 363 at 6 (Reply), *with* D.I. 363-1 at 5 (no longer including such language). As CareDx notes, Natera objected to this provision as vague. (D.I. 363 at 6.) An inherently subjective term like "colorably different" does not "reasonably" describe the "act or acts" restrained where prior restraints on speech are at issue. CareDx's only argument for this language is that courts "regularly" use it—but it cites only a single case (D.I. 363 at 6 (citing *Gavrieli Brands LLC v. Soto Massini (USA) Corp.*, No. 18-cv-462 (MN), 2020 WL 1443215 (D. Del. Mar. 24, 2020)), and the provision in that case applied to *patents*, where "colorably different" is the "proper" test under Federal Circuit precedent. *Gavrieli*, 2020 WL 1443215, at *9 (rejecting challenge to "'not colorably different' language in the patent-related provision"). CareDx provides no authority to support including such a vague prior restraint in a false advertising cases, and Natera is aware of none.

First, although CareDx now proposes to limit its injunction to claims "based on the scientific support presented at trial," its new proposal remains fatally overbroad. Numerous papers were "presented" at trial, including Sigdel, Bloom, Huang, and Altug. For all but one of the challenged "False Advertising Claims," CareDx's sole theory of liability was that the claims were false because they were based on "unreliable comparisons" between *Sigdel* and *Bloom*. (*See, e.g.*, 3/14, 1348:21-1369:6.) CareDx's proposed injunction, however, sweeps much broader—it suggests that Natera may not make these claims based on *any* comparison to Bloom, Huang, or Altug, *no matter* what the comparator study is or how reliable the comparison, either present or future. To ensure that Natera is not "restrain[ed]…from engaging in lawful business activities," *Mallet & Co. Inc. v. Lacayo*, 16 F.4th 364, 390 (3d Cir. 2021), any injunction should be limited to advertising claims that were actually at issue.

The *Castrol* cases cited by CareDx (D.I. 363 at 6-7) are inapposite because they involved bare competitive superiority claims, and direct-consumer television marketing. In both cases, the advertisements asserting bare superiority claimed, at most, that unidentified "tests proved" the propositions. *See Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939 (3d Cir. 1993); *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 59-60 (2d Cir. 1992). This case is different—because the alleged false advertising claims involved *specific studies* directed to sophisticated transplant nephrologists.

By tying its injunction to the "scientific support identified at trial," CareDx concedes that *Castrol* is inapplicable here.

In addition, CareDx's proposed reading of the *Castrol* decisions—as extending beyond bare superiority claims—would risk pressing this Court into service as a permanent board of review for the "reliability" of future research. CareDx's claims were based on critiques of Sigdel and whether Sigdel's results could be "reliably compar[ed]" to those from Bloom. Any injunction should be correspondingly limited to claims based on the Sigdel paper.

Second, CareDx argues that, because the agreed-upon jury verdict form included images it proposes to reproduce in the Permanent Injunction, Natera is bound to accept those images as the measure of its permanently restrained speech. (D.I. 363, at 8.) CareDx cites no authority for that proposition, because there is none. The scope of an injunction is left to the Court's discretion. *See, e.g.*, *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 206 (3d Cir. 2014) ("District Courts are afforded considerable discretion in framing injunctions." (quotation marks omitted)). The images assisted the jury by supplying *context* for the allegedly false claims—but they also included assertions that CareDx never challenged (*e.g.*, "5x higher repeatability at 0.6% donor fraction (CV)") or that the jury found *not* to be false (*e.g.*, "First test to consistently detect subclinical rejection"). (*See* D.I. 357 at 5.) Furthermore, the "falsity" of the purported pediatric claim (D.I. 329 at 13) was

necessarily based on an *inference*—CareDx's reproduction of the image without articulating a *statement* would fail to enjoin with specificity what it asserts to be false.

To provide the requisite specificity and detail, any injunction must identify the specific statements CareDx contended were false. Indeed, CareDx listed those statements in its Opening Brief (although its articulation was overbroad, *see* D.I. 357 at 4-5), and acknowledges that these statements are what it seeks to enjoin. (D.I. 363 at 2 n.1 ("CareDx maintains that all of the false statements identified in its Opening Brief should be enjoined.")). Based on the verdict form, trial record, and CareDx's post-trial briefing, Natera understands the false "statements" at issue, and the corresponding numbers in CareDx's revised proposed injunction, to be:

- "More sensitive and specific than current assessment tools across all types of rejection," based on a comparison of Prospera and AlloSure performance results reported in Sigdel and Bloom (1);
- "Unparalleled precision," based on a comparison of Prospera and AlloSure performance results reported in Sigdel and Bloom (2);
- Prospera has higher sensitivity and higher area under the curve (AUC) than AlloSure, based on a comparison of Prospera and AlloSure performance results reported in Sigdel and Bloom (3, 4, 5);
- Prospera has higher NPV than AlloSure and misses 3x fewer rejections, based on a comparison of Prospera and AlloSure performance results reported in Sigdel and Bloom (6, 7);
- Prospera has "[h]igher area under the curve; driven by superior clinical data," based on a comparison of Prospera and AlloSure performance results reported in Sigdel and Bloom (8); and

- Prospera is "highly sensitive" in patients "[b]elow 18 years of age," based on results reported in Sigdel (9).

If the Court is inclined to permanently enjoin Natera, and to consider CareDx's untimely proposal in reply, it should limit and define the scope of the injunction by tailoring it to the statements at issue, as bulleted above.

Finally, CareDx's revised injunction is overbroad to the extent it would require Natera to "identify[] the scientific support" if it intends to make comparative claims based on future scientific research. (D.I. 363-1 at 5.) Because CareDx did not make this request in its initial proposed injunction, it is waived. Its Reply Brief cites no authority for an order compelling speech in this way, and makes no substantive argument for including this provision. It only notes in passing that its revised proposal *would* compel the speech, without articulating any justification for doing so. (D.I. 363 at 7, 11.)

Equally problematic, CareDx's proposal that this Court preclear Natera's advertising risks further conscripting this Court as a permanent scientific review board. CareDx's baseless demand, which is waived, improperly burdens the Court.[3]

[3] It is also vague. CareDx does not explain what it means by "identifying the scientific support," and so gives no indication of when it would move for contempt sanctions for failure to sufficiently "identify" support by its (undisclosed) standards.

II. CAREDX CONTINUES TO SEEK RELIEF TO WHICH IT IS NOT ENTITLED.

Even as it ostensibly narrows its requested relief, CareDx continues to seek an injunction restraining speech that was never at issue— *any* reference to Prospera's use in pediatric patients, and *any* use of the phrase "unparalleled precision." (D.I. 363 at 8-11.) What is more, CareDx's revised injunction now also improperly seeks to dictate the citation practices of Natera's advertising in perpetuity. CareDx's insistence on overbreadth reinforces why any injunction must be "narrowly tailored," *Mallet*, 16 F.4th at 389, and "carefully addressed to the circumstances of the case." *De Simone v. Alfasigma USA, Inc.*, 847 F. App'x 174, 183-84 (4th Cir. 2021) (non-precedential) (quotation marks omitted).

The overbreadth of CareDx's proposed injunction is starkly illustrated by its contention that the Tweet claiming validation in pediatric patients is "literally false." (D.I. 363 at 10.) That Tweet, and the claim in it, were never at issue in this case. CareDx argued that it was false to claim Prospera is "highly sensitive" in patients under 18 because the results reported in the Sigdel paper did not support it. (3/9, 155:5-156:3 (Weisbord: disagrees with slide because Sigdel reported "children did not have any rejections" so it is not "possible to calculate a sensitivity"); 3/14, 1436:4-9 (identifying source of falsity as Sigdel paper; "when you think about

the…pediatric claims…, it is not like there's something else in terms of analysis").[4] Yet despite arguing at trial that Natera had "[no]thing else in terms of analysis" to support such a claim, CareDx now argues that a *different* statement based on *subsequent* data and analysis not presented at trial is *still false*—a position irreconcilable with its assurance that "only claims based on the scientific data presented at trial will be enjoined." (D.I. 363 at 10-11.) CareDx's effort to block or chill speech that was never addressed in this litigation should be rejected, as should its attempt to police Natera's scholarship citation practices indefinitely.

CareDx also argues that it "proved, and the Jury found…Natera's superiority claim of '[u]nparalleled precision' is literally false." (D.I. 363 at 8-9.) But CareDx did not contend that this phrase was false when used in the abstract, when used in reference to serum creatinine, or when otherwise used in advertising that does not include the comparisons between Prospera and AlloSure that the jury found false. Rather, CareDx consistently argued that "unparalleled precision" was false in a two-page advertising spread connected to four surrounding comparative claims about AlloSure. (*See* 3/9, 151:8-23 (Weisbord: "[T]here are four quadrants. All of them are pointing to this center circle that says 'unparalleled precision.'"); 3/14, 1369:1-3 ("Here, unparalleled precision that incorporates all four [comparisons]. It has a line to each."), 1378:13-18 ("So unparalleled precision, we're the best. And then it ties

[4] Citations to March 9, 2022 transcript are to the unofficial transcript.

into the four quadrants in that spread that we saw."). The image in the verdict form illustrated that context—and it was only in that context the jury found the advertising false. Further enjoining the phrase "unparalleled precision" in contexts where it was not found false would be overbroad.

CONCLUSION

The Court should deny CareDx's Motion for a Permanent Injunction. To the extent any injunction is issued, it must be narrowly tailored to the specific performance claims and comparisons that were litigated and that the jury found to be false, as outlined in the bullet points set forth in Section I.

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June 10, 2022

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations specified in the Court's Standing Order Regarding Briefing in All Cases. According to the word processing system used to prepare this document, the brief contains 2,317 words. This total excludes the cover page, tables, signature block, certification, and certificate of service.

I further certify that this brief complies with the typeface requirements set forth in the Court's Standing Order Regarding Briefing in All Cases because this brief was prepared using Microsoft Word in 14-point Times New Roman font.

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CERTIFICATE OF SERVICE

I hereby certify that on June 10, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 10, 2022, upon the following in the manner indicated:

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